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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,933	10/20/2003	Helmut D. Link	246472006000	8319

7590 02/12/2007  
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EXAMINER
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COMSTOCK, DAVID C

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,933	<b>Applicant(s)</b> LINK, HELMUT D.	
	<b>Examiner</b> David Comstock	<b>Art Unit</b> 3733	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,5,7,8 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,7,8 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's arguments in the Appeal Brief filed 27 September 2006 have been considered. However, Examiner has become aware of a ground of rejection that has not been addressed. Accordingly, the finality of the last Office action has been withdrawn. The new and outstanding grounds of rejection and response to Applicant's arguments are set forth below.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the "hinge radius" as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either

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"Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7 and 12-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The subject matter of these claims is not patent eligible subject matter because it is directed to a judicial exception to 35 USC 101. The claims fail to require a physical transformation and do not produce a useful, concrete and tangible result. The step of "providing ... a prosthesis..." does not necessarily require a physical transformation and does not necessarily produce a useful, concrete and tangible result, since this could refer simply to, for example, an instruction, a hypothetical premise, or perhaps to the way the device is allowed to go forward (i.e. by approval). It is further noted that a step of actually implanting the prosthesis is not present.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,895,428 (Berry).

Berry discloses a cervical intervertebral prosthesis system comprising different prostheses 11 each having a pair of slide surfaces 29, 43 configured to form a hinge (Figs. 2 and 12-19). The different prostheses have different positions of the center of hinge movement and slide surfaces with different radii of curvature (Figs. 2 and 12 and col. 8, line 18 - col. 9, line 8). The prostheses of the system have different extents in an anterior-posterior direction.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,895,428 (Berry).

Berry discloses the claimed invention except for explicitly disclosing providing slide surface radii of below 15 mm or 18 mm for a prosthesis and over 18 mm for another prosthesis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the prostheses with a slide surface radii below 15 mm or 18 mm for one prosthesis and over 18 mm for another prosthesis, since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e. different prostheses having different sizes of slide surface radii, discovering the optimum or workable ranges of the same involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Response to Arguments***

First, by way of clarification of terminology used by Applicant, the following is noted. Figure 1 of Applicant's invention, reproduced below, shows *slide surface radius* 17. The slide surface radius extends from the *center of hinge movement* 18 to the slide surface. Thus, slide surface radius is inextricably defined with respect to the center of hinge movement. Therefore, it necessarily follows that if the different prostheses have different slide surface radii of curvature (which they do in Berry, as set forth above), they must also have corresponding different centers of hinge movement. Therefore, any argument that Berry does not disclose "centers of hinge movement" is without merit.\*\*

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\*\* It is noted that "*hinge radius*" is another measurement and is not set forth in the remaining rejected claims and should not be confused with *center of hinge movement* or *slide surface radius*. However, even if *hinge radius* were in the claims, again, it would inherently be set forth, since it is defined as the distance from the *center of hinge movement* to the geometric midpoint of the prosthesis.

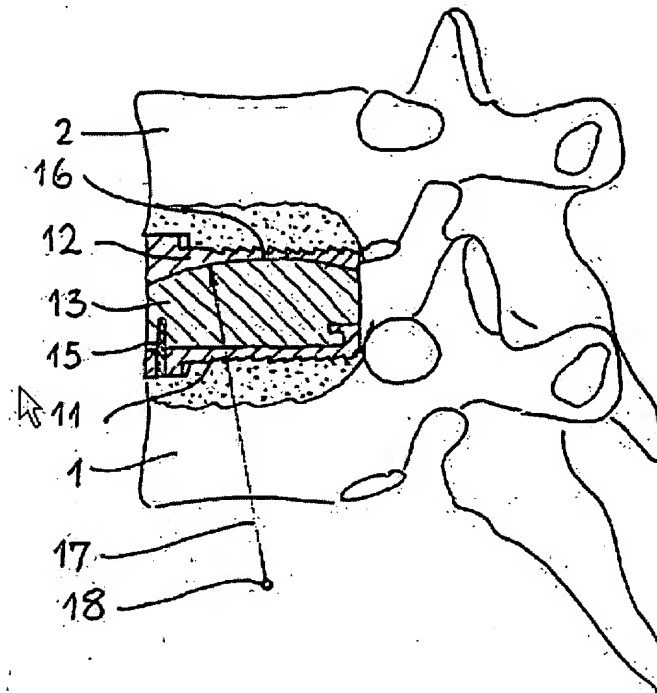


Figure 1

Next, in response to Applicant's argument that the device of Berry teaches the opposite of the claimed system, and with respect to claim 8, Examiner acknowledges that Berry discloses prostheses having slide surfaces with greater or increasing radii of curvature going from a cranial to caudal direction, as shown in Figure 12. However, the way in which Applicant's claimed prostheses are intended to be used (i.e. the way in which they are intended to be selected with respect to the intervertebral disks of a spine) does not result in a structural difference between the claimed invention and the prior art. They both are directed to the same structural elements (i.e. different cervical intervertebral prostheses with hinges having different positions of the center of hinge

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movement and with slide surfaces with different radii of curvature). See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). In addition, it is noted that something that is old does not become patentable upon the discovery of a new property. The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Thus, merely inserting the cervical intervertebral prostheses of Berry, which have the same claimed structural features, in a manner according to the intended use set forth in apparatus claim 8 (i.e. with a greater radius of curvature in a cranial direction, etc.), should not render the claim allowable.

In response to Applicant's argument that the claimed invention is not merely a pair of prostheses, but rather a "system" in which the prostheses are arranged in a specified manner, Examiner appreciates this point. However, there is no structure, for example, that connects the prostheses together in some specified manner, or the like. Instead, they are simply separate prostheses that are intended to be placed in a certain location. Thus, the "system" is that there are more than one and they are intended to be placed in a certain location in the spine. Berry discloses more than one prosthesis, and the intended use of Applicant's "system" does not distinguish it structurally from the prostheses of Berry. It is noted that Applicant's argument that the prostheses of the invention cannot be implanted "upside down" is absolutely irrelevant to the claimed subject matter and is even misleading. There is no reason to turn any implants "upside down" for the present claims to read on Berry. Perhaps, Applicant was attempting to



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drive home the point that a "system" is being claimed. However, again, there is no structure connecting the prostheses that would necessitate turning any prostheses upside down in order to satisfy the statements of intended use.

Applicant's final argument with regard to independent claim 8 asserts, without any explanation or support: "Furthermore, the prostheses making up applicant's claimed prosthesis system are different in structural respects that Berry does not disclose, either expressly or inherently." (Page 7, lines 4-6.) Respectfully, Examiner notes that the only thing that is not disclosed either expressly or inherently is what these purported "differen[ces] in structural respects" that Berry allegedly does not disclose might be. Whatever they might be, they are not in claim 8.

With regard to the obviousness rejection of claims 4 and 5, Applicant argues that there is allegedly "no evidence at all" that persons of ordinary skill in the art would have had any reason to choose or optimize the slide surface radii. However, this is incorrect on its face. A person of ordinary skill in the art knows that vertebral columns come in different particular shapes and different sizes (e.g., deformed, damaged, old, young, male, female, human, animal, etc.). Thus, Berry discloses using tomographic imaging to determine the appropriate size of prosthesis (col. 4, lines 19-23). Applicant takes pains to argue that size is not tantamount to radius of curvature. However, a person of ordinary skill in the art can also appreciate that if the device is scaled down or scaled up in size, the radius of curvature will change by the same proportion and vice versa. Otherwise, the prosthesis would have incoherent dimensions.

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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



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